

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER
WHEN USED ACCORDING TO DIRECTIONS**

3981. Misbranding of vaginal suppositories. U. S. v. 131 Boxes * * *. (F. D. C. No. 34396. Sample No. 39888-L.)

LIBEL FILED: December 24, 1952, Southern District of California.

ALLEGED SHIPMENT: On or about September 29, 1952, by the Dr. J. A. McGill Co., from Chicago, Ill.

PRODUCT: 131 boxes of *vaginal suppositories* at Los Angeles, Calif. Examination showed that the product contained approximately 47 percent ammonium alum and 10.6 percent borax in a fatty base. Each box contained a copy of a leaflet entitled "Dr. J. A. McGill Co.'s Suppositories."

LABEL, IN PART: (Box) "Contents 6 Suppositories * * * Orange Blossom Suppositories * * * Alum - Borax - Petrolatum * * * Dr. J. A. McGill Co. * * * Chicago 16, Ill."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement appearing in the labeling of the article "For Simple Irritations Of The Vaginal Tract" was false and misleading. The statement represented and suggested that the article was an adequate and effective treatment for diseases of the vaginal tract which are manifested by irritation of the vaginal tract, whereas the article was not an adequate and effective treatment for these diseases.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil at bedtime, insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days."

DISPOSITION: January 26, 1953. Default decree of condemnation and destruction.

3982. Misbranding of Mam-Zelle syringe and Mam-Zelle tablets. U. S. v. 11 Cartons, etc. (F. D. C. No. 34656. Sample No. 18577-L.)

LIBEL FILED: February 17, 1953, District of Arizona.

ALLEGED SHIPMENT: On or about November 29, 1952, by the Barclay Pharmaceutical Products Co., from Pasadena, Calif.

PRODUCT: 1 carton containing 12 12-tablet bottles of *Mam-Zelle tablets*, and 11 cartons, each containing 2 packages, and each package consisting of a cardboard box containing 1 *Mam-Zelle syringe* and 1 12-tablet bottle of *Mam-Zelle tablets*, at Phoenix, Ariz. There were enclosed in each package a circular designated "For women Strictly personal," and a circular designated "How To Use *Mam-Zelle* Effervescent Feminine Hygiene Syringe Unit."

The *Mam-Zelle syringe* consisted of a two-piece plastic cylinder which was closed except for a valve-operated exit tube which connected through a short piece of rubber tubing to a plastic nozzle having eight small holes at the sides and one small hole at its tip. In operation, the plastic cylinder was charged by filling with water and placing one of the *Mam-Zelle tablets* in position. After the assembling of the cylinder, the water and tablet were brought into contact whereby the effervescing-type tablet dissolved with the liberation of